

REMARKS

Claims 1-29 are pending in the present application.

Claims 1-29 have been rejected.

Claims 1, 5-6, 8-9, 11, 15-16, 18-19, 21-26 and 28-29 have been amended.

Claims 1-29 remain in the case.

Reconsideration of Claims 1-29, as amended, is respectfully requested.

35 U.S.C. § 102(b) Anticipation

In Paragraph 2 on Pages 2-3 of the April 7, 2003 Office Action, the Examiner rejected Claims 1-2, 4, 6, 11-12, 14 and 16 under 35 U.S.C. § 102 (b) as being anticipated by United States Patent No. 5,123,425 to *Shannon, Jr. et al.* (hereafter "*Shannon*").

The Examiner stated "In regards to claims 1 & 11, Shannon discloses an apparatus for terminating an obstructive sleep apnea even before cessation of breath occurs comprising at least one microphone (24 and supporting text) which detects breathing sounds and which generates signals representative of such; a controller (20) coupled to the microphone capable of receiving such breathing sound signals and identifying signals indicative of the onset of obstructive sleep apnea / (e.g partially occluded airway) event even before cessation of breathing occurs and capable of generating an alarm signal (col.3 lines 25-50), and a stimulus generator (26 & 28 and supporting text) capable of receiving such alarm signals creating a stimulus to cause said person to move in a

manner that causes said obstructive sleep apnea / (e.g. partial occlusion) event to terminate before cessation of breathing occurs.” (April 7, 2003 Office Action, Paragraph 2, Page 2).

The Applicants respectfully traverse the Examiner’s assertion that the *Shannon* reference discloses an apparatus for terminating an obstructive sleep apnea event even before cessation of breath occurs. The *Shannon* reference does not disclose this feature. Cessation of breathing must occur before the *Shannon* apparatus can detect the presence of an obstructive sleep apnea event.

The Applicants also respectfully traverse the Examiner’s assertion that the *Shannon* apparatus is capable of identifying signals that indicate “the onset of obstructive sleep apnea / a partially occluded airway event.” The Applicants’ invention is capable of identifying the “onset” (i.e., the beginning) of an obstructive sleep apnea event before the obstructive sleep apnea event (i.e., cessation of breathing) actually occurs. The *Shannon* apparatus is not able to do this. Cessation of breathing must occur before the *Shannon* apparatus can detect the presence of an obstructive sleep apnea event. Further, the *Shannon* reference does not mention “a partially occluded airway event.” There is nothing in *Shannon* that suggests or event hints at “a partially occluded airway event” that occurs at the onset of an obstructive sleep apnea event.

In order to clarify that the Applicants’ invention terminates a physiological process that causes cessation of breathing due to an obstructive sleep apnea event before cessation of breathing occurs, the Applicants have amended Claims 1, 5-6, 8-9, 11, 15-16, 18-19, 21-26 and 28-29. The *Shannon* apparatus does not teach the concept of detecting the onset of an obstructive sleep

apnea event before cessation of breathing occurs. Therefore, the Applicants respectfully submit that the amended claims of this patent application are not anticipated by *Shannon*.

It is clear from the language of the *Shannon* reference that *Shannon* uses the word “onset” to mean the beginning of an actual apnea event when breathing ceases. For example, the output of the *Shannon* sensor “is conditioned and interpreted, and used to determine whenever an apnea event is initiated.” (*Shannon*, Col. 2, Lines 42-44) (Emphasis added). That an “apnea event” requires the “cessation of breathing” may be seen from the language of Claim 1 of *Shannon*: “An apparatus for treating obstruction of an upper air passageway of a patient” (Emphasis added).

The *Shannon* reference does not disclose the concept of detecting the onset of an apnea event before cessation of breathing occurs. Like a number of prior art systems *Shannon* is capable of detecting an apnea event by determining the presence or absence of breathing. *Shannon* does not indicate the existence of an apnea event if breathing is present. “Sensor 24 is used to determine the onset of an apnea episode. In the preferred embodiment, this is a microphone or motion sensor which generates an electrical signal corresponding to the presence of breath or snoring sounds.” (Emphasis added) (*Shannon*, Column 3, Lines 25-29). The electronic circuit 200 of *Shannon* activates a stimulation signal (using on-time timer 208, ramp generator 209 and pulse generator 210) when sensor 24 no longer detects any “presence of breath or snoring sounds.” This shows that in *Shannon* the onset of an apnea event begins when cessation of breathing occurs. *Shannon* does not

analyze breath sounds that are associated with an onset of an apnea event before cessation of breathing occurs. *Shannon* does not detect a signal that indicates that an apnea event will occur.

The Examiner stated that “At the outset the examiner notes that applicant points to no empirical differences in structure between the prior art device and the instantly claimed invention.” (April 4, 2003 Office Action, Page 8). The Applicants respectfully traverse this assertion of the Examiner. In the Applicants’s Amendment dated January 13, 2003, the Applicants pointed out that the *Shannon* reference comprises an electronic circuit 200 that activated a stimulation signal (using on-time timer 208, ramp generator 209 and pulse generator 210) when sensor 24 no longer detects any “presence of breath or snoring sounds.” *Shannon* sends a signal to an integrator 206 to create a “level representing the integrated sensor signal.” (*Shannon*, Column 4, Lines 35-36). This “level” is compared to a threshold value set by threshold adjust 216. “This ensures that whenever the integrated circuit levels exceeds the threshold set by threshold adjust 215, a signal is set to on-time timer 208 which initiates a ramp generator 209 for the duration as set by trigger adjust 212.” (*Shannon*, Column 4, Lines 38-42). The “levels” that are created and compared to a preset threshold value in the *Shannon* device are not equivalent to the signal patterns that are generated and used in the Applicants’ invention.

This description of the *Shannon* electronic circuit 200 shows that (1) the *Shannon* device is structurally different from the Applicants’ invention, and (2) the *Shannon* device is not capable of detecting the existence of a partially occluded airway or performing the functions of the Applicant’s

invention. *Shannon* does not disclose how the threshold adjust 216 obtains a value of threshold. There is nothing in *Shannon* that teaches or suggests that the *Shannon* threshold is anything other than a “breathing” versus “not breathing” threshold. The Applicants respectfully submit that it is not possible to use the *Shannon* device to perform the functions of the Applicants’ invention. If the airway of a person was partially occluded, the threshold detection circuit of the *Shannon* device could not detect the partial occlusion.

The Examiner stated that “Applicant points to no structure in his invention that flows as a distinction from the device of the prior art.” (April 7, 2003 Office Action, Page 8). The Applicants respectfully traverse this assertion of the Examiner. Claim 1 claims a controller that is capable of identifying “at least one signal pattern” that is associated with a breathing pattern of a person that occurs at the onset of a physiological process that, unless terminated, causes cessation of breathing to occur due to an obstructive sleep apnea event. The *Shannon* device is not capable of identifying such signal patterns. The Shannon device does not have any hardware that has the capability of the controller of the Applicants’ invention.

The Examiner also stated that “The there is no teaching in the prior art that the airway must be fully obstructed before it will act upon ameliorating an apneic event.” (April 7, 2003 Office Action, Page 8). The Applicants respectfully traverse this statement of the Examiner. The very definition on “apnea” requires that breathing cease. An “apneic event” is one which causes breathing to cease. An “apneic event” is one in which an airway is fully obstructed.

The Examiner stated “The plain language of applicant’s claim pre-supposes the existence of a sleep apnea event, i.e. obstruction, not just onset.” (April 7, 2003 Office Action, Page 9). In response, the Applicants have amended the claims to clarify that the Applicant’s invention terminates the physiological process that, unless terminated, will lead to the complete obstruction of the airway caused by an obstructive sleep apnea event.

The Examiner stated “The Shannon reference makes no such correlation to onset empirically meaning the airway is completely obstructed, contrary to applicant’s assertion that this is clear. None of the fragment points suggest, let alone clearly state this correlation of terms.” (April 7, 2003 Office Action, Page 9). The Applicants respectfully traverse this assertion of the Examiner. The portions of the *Shannon* reference cited above make it clear that *Shannon* is only capable of detecting cessation of breathing. There are no portions of *Shannon* that suggest otherwise. *Shannon* does not detect and is not capable of detecting a partial obstruction of an airway.

Further, the Applicants have amended the claims to claim a stimulus generator that causes the person with an obstructed airway to move the person’s head backwards to terminate the physiological process that is causing the obstructed airway. The *Shannon* reference teaches stimulation of the genioglossus and related muscle groups. (*Shannon*, Column 4, Lines 43-50). The *Shannon* approach directly produces muscle contraction of the muscle tissue of the upper air passageway. (*Shannon*, Claim 1). The Applicant’s method is superior to that of *Shannon* because direct electrical stimulation of the genioglossus and related muscle groups may simultaneously

stimulate a plurality of sets of muscles that work against each other (e.g., in the same manner as the biceps and the triceps in the arm work against each other). The *Shannon* reference makes no mention of this problem. The Applicants' invention avoids this problem altogether.

For the reasons set forth above, Applicants respectfully submit that amended Claim 1 contains unique and novel limitations and that amended Claim 1 is not anticipated by the *Shannon* reference. Applicants also respectfully submit that Claim 11, Claim 21, Claim 28 and Claim 29 also contain unique and novel limitations and that Claim 11, Claim 21, Claim 28 and Claim 29 are not anticipated by the *Shannon* reference. Claims 2 through 10 depend from and contain all the unique and novel limitations contained in amended Claim 1. Claims 12 through 20 depend from and contain all the unique and novel limitations contained in amended Claim 11. Claims 22 through 27 depend from and contain all the unique and novel limitations contained in amended Claim 21. Therefore, Claims 1-29, as amended, are not anticipated by the *Shannon* reference.

The Applicants respectfully request that the rejection of Claims 1-2, 4, 6, 11-12, 14 and 16 under 35 U.S.C. §102(b) as anticipated by the *Shannon* reference be withdrawn and that Claims 1-29, as amended, be passed to issue.

35 U.S.C. § 103(a) Obviousness

In Paragraph 4 on Pages 3-4 of the April 7, 2003 Office Action, the Examiner rejected Claims 7-8, 10, 17-18, 20-22 and 24-29 under 35 U.S.C. § 103 (a) as being obvious in view of *Shannon*.

In Paragraph 5 on Pages 4-5 of the April 7, 2003 Office Action, the Examiner rejected Claims 9 and 19 under 35 U.S.C. § 103 (a) as being unpatentable over *Shannon* in view of United States Patent No. 5,058,600 to *Schechter et al.* (hereafter “*Schechter*”).

In Paragraph 6 on Pages 5-6 of the April 7, 2003 Office Action, the Examiner rejected Claims 3 and 13 and 23 under 35 U.S.C. § 103 (a) as being unpatentable over *Shannon* in view of United States Patent No. 5,652,566 to *Lambert*.

In Paragraph 7 on Pages 6-7 of the April 7, 2003 Office Action, the Examiner rejected Claims 5 and 15 under 35 U.S.C. § 103 (a) as being unpatentable over *Shannon* in view of United States Patent No. 6,011,477 to *Teodorescu et al.* (hereafter “*Teodorescu*”).

The Applicants respectfully traverse (1) the Examiner’s rejection of Claims 7-8, Claim 10, Claims 17-18, Claims 20-22 and Claims 24-29 as being obvious in view of *Shannon*, (2) the Examiner’s rejection of Claim 9 and Claim 19 as being obvious in view of *Shannon* and *Schechter*; (3) the Examiner’s rejection of Claim 3, Claim 13 and Claim 23 as being obvious in view of *Shannon* and *Lambert*; and (4) the Examiner’s rejection of Claim 5 and Claim 15 as being obvious in view of *Shannon* and *Teodorescu*. The Applicants respectfully request the Examiner to withdraw

the rejections of the above referenced claims in view of the [[Applicants' amendments and]] the Applicants' remarks concerning the prior art references.

During *ex parte* examinations of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness is established does the burden shift to the applicant to produce evidence of non-obviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 USPQ 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art,

to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not be based on an applicant's disclosure. MPEP § 2142.

Applicants respectfully submit that the Patent Office has not established a *prima facie* case of obviousness with respect to the Applicants' invention. The Applicants direct the Examiner's attention to amended Claim 1 which shows novel and unique features:

1. (Currently amended) An apparatus for terminating a physiological process that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated before cessation of breathing occurs, wherein the apparatus comprises:

at least one microphone capable of being acoustically associated with said person, said microphone capable of detecting breathing sounds within said airway of said person and capable of generating signals representative of said breathing sounds;

a controller coupled to said at least one microphone and capable of receiving said signals, said controller capable of identifying within said signals at least one signal pattern that is associated with a breathing pattern of said person that occurs at the onset of, before cessation of breathing occurs, and capable of generating an alarm signal in response thereto; and

a stimulus generator coupled to said controller, said stimulus generator capable of receiving said alarm signal from said controller, and in response thereto, creating a stimulus to cause said person to move said person's head backwards to terminate said physiological process before cessation of breathing occurs.

The Applicants reiterate the arguments that the Applicants have previously made with respect to the *Shannon* reference. There is no teaching, suggestion or even a hint in the *Shannon* reference

concerning the Applicants' novel and unique concept of "terminating a physiological process that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of the airway due to an obstructive sleep apnea event, wherein the physiological process is terminated before cessation of breathing occurs." A teaching or suggestion to make the Applicants' invention and a reasonable expectation of success is not found in the *Shannon* reference (or in any other prior art reference). Therefore, the Applicants' invention is not *prima facie* obvious in view of the *Shannon* reference.

The Examiner has stated that "In regard to claims 9 & 19, Shannon substantially discloses the instant application's claimed invention to include the capability of detecting a breathing signal associated with the onset of an obstructive sleep apnea event, but does not explicitly disclose using software with Fast Fourier Transform (FFT) analysis. However, Schechter discloses such (Note abstract statement that acoustic signals are processed using FFT). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Schechter and used them with the device of Shannon. The suggestion/motivation for doing so would have been to effectively process the acoustical data for diagnostic analysis. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention." (April 7, 2003 Office Action, Pages 4-5). The Applicants respectfully traverse the Examiner's assertion that *Shannon* substantially discloses the Applicants' claimed invention.

In particular, the Applicants respectfully traverse the Examiner's assertion that *Shannon* teaches all the limitations of Claims 9 and 19 except that the software analyzes the signals using a Fast Fourier Transform analysis. The Applicants also respectfully traverse the Examiner's assertion that it would have been obvious to combine the *Schechter* reference with the *Shannon* reference.

Claim 9 depends from amended Claim 8 (which, in turn, depends from amended Claim 1). Claim 19 depends from amended Claim 18 (which, in turn, depends from amended Claim 11). As previously described, *Shannon* does not analyze breath sounds that are associated with an onset of an apnea event before cessation of breathing occurs. *Schechter* discloses an expert diagnostic system that is designed to detect pathological obstructions and not temporary obstructions such as an obstructive apnea event. Even if *Schechter* apparatus could detect an obstructive apnea event it would not detect the obstructive apnea event until after the obstructive apnea event had occurred (i.e., until after the cessation of breathing had occurred).

The *Schechter* reference does not disclose a signal analysis template for detecting an obstructive apnea event or for detecting an onset of an obstructive apnea event. That is, there is no signal analysis mechanism in *Schechter* for detecting an obstructive apnea event. Therefore, unlike the Applicants' invention, the *Schechter* system will identify breath sounds that are associated with an "onset" of an obstructive apnea event as "normal" breath sounds. *Schechter* does not disclose, suggest, or even hint at the concept of using of spectral analysis techniques to detect an obstructive apnea event or to detect an onset of an obstructive apnea event.

Under the applicable patent law, there must be some teaching, suggestion or motivation to combine the *Shannon* reference and the *Schechter* reference. “When a rejection depends on a combination of prior art references, there must be some teaching, or motivation to combine the references.” *In re Rouffet*, 149 F.3d 1350, 1355-56, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). “It is insufficient to establish obviousness that the separate elements of an invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the references.” *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997). The Applicants respectfully submit that there exists no teaching, suggestion or motivation in the prior art to combine the teachings of the *Shannon* reference and the teachings of the *Schechter* reference.

When two references are combined the combination of the references must teach or suggest all the claim limitations. In the present case, even if the *Shannon* reference were combined with the *Schechter* reference, the combination of the *Shannon* reference and the *Schechter* reference would not teach, suggest or even hint at the Applicants’ invention. This is because, as previously described, the *Schechter* reference does not teach, suggest, or even hint at the Applicants’ concept of using of spectral analysis techniques to detect an obstructive apnea event or to detect an onset of an obstructive apnea event. The Applicants respectfully submit that the rejections of Claims 9 and 19 under 35 U.S.C. §103(a) combining the *Shannon* reference and the *Schechter* reference should be withdrawn.

With respect to the rejection of Claim 3, Claim 13 and Claim 23, the Examiner has stated that “[I]t would have been obvious to one of ordinary skill in the art to have taken the features of Lambert and used them with the device of Shannon. The suggestion/motivation for doing so would have been to provide additional/redundant alarm systems, insuring the user is stimulated.” (April 7, 2003 Office Action, Pages 5-6). The Applicants respectfully traverse the Examiner’s assertion that it would be obvious to combine the teaching of *Shannon* with the teachings of *Lambert*.

Claim 3 depends from amended Claim 1. Claim 13 depends from amended Claim 11. Claim 23 depends from amended Claim 21. Each of the amended independent claims contain a claim limitation restricting the detection of an onset of an obstructive apnea event to a time “before cessation of breathing occurs.” This element is not present in *Shannon* or in *Lambert*.

Further, the reliability that is provided by the redundant alarm system of *Lambert* is not needed for the Applicants’ invention. *Lambert* states that “Reliability is a critical requirement for effective alarm systems. For example, in a hospital, a patient’s life often depends on the effective operation of a medical monitor alarm.” (*Lambert*, Col. 1, Lines 1-13). The Applicants’ invention is not a life saving monitor because people do not die from an episode of obstructive apnea. They always re-open an obstructed airway with the body’s gasping reflex. Therefore, the level of reliability provided by the *Lambert* system is not required.

Under the applicable patent law, there must be some teaching, suggestion or motivation to combine the *Shannon* reference and the *Lambert* reference. Further, when two references are

combined the combination of the references must teach or suggest all the claim limitations. In the present case, even if the *Shannon* reference were combined with the *Lambert* reference, the combination of the *Shannon* reference and the *Lambert* reference would not teach, suggest or even hint at the Applicants' invention. This is because, as previously described, the *Shannon* reference does not teach, suggest, or even hint at the Applicants' concept of detecting an apnea event "before cessation of breathing occurs."

The Applicants respectfully submit that the rejections of Claim 3, Claim 13 and Claim 23 under 35 U.S.C. §103(a) combining the *Shannon* reference and the *Lambert* reference should be withdrawn.

With respect to the rejection of Claim 5 and Claim 15, the Examiner has stated that "At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Teodorescu and used them with the device of Shannon. The suggestion/motivation for doing so would have been to give the user more range/freedom of movement during use of the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention." (April 7, 2003 Office Action, Pages 6-7).

Claim 5 depends from amended Claim 1. Claim 15 depends from amended Claim 11. Each of the amended independent claims contain a claim limitation restricting the detection of an onset

of an obstructive apnea event to a time “before cessation of breathing occurs.” This element is not present in *Shannon* or in *Teodorescu*.

Further, the supposed suggestion/motivation for combining the *Shannon* reference and the *Teodorescu* reference was said to be to give the user more range/freedom of movement during use of the device. But the user of the device is asleep during the time that the device is being used. The user is not moving in a manner that requires “more range/freedom of movement.”

Under the applicable patent law, there must be some teaching, suggestion or motivation to combine the *Shannon* reference and the *Teodorescu* reference. Further, when two references are combined the combination of the references must teach or suggest all the claim limitations. In the present case, even if the *Shannon* reference were combined with the *Teodorescu* reference, the combination of the *Shannon* reference and the *Teodorescu* reference would not teach, suggest or even hint at the Applicants’ invention. This is because, as previously described, the *Shannon* reference does not teach, suggest, or even hint at the Applicants’ concept of detecting an apnea event “before cessation of breathing occurs.”

The Applicants respectfully submit that the rejections of Claim 5 and Claim 15 under 35 U.S.C. §103(a) combining the *Shannon* reference and the *Teodorescu* reference should be withdrawn.

The Applicants respectfully submit that Claims 1-29, as amended, are all patentable over the *Shannon* and the *Schechter* reference and the *Lambert* reference and the *Teodorescu* reference

whether taken individually or in combination. The Applicants respectfully request that the rejection of Claims 1-29 be withdrawn and that Claims 1-29 be passed to issue.

The Applicants deny any statement, position or averment of the Examiner that is not specifically addressed by the foregoing argument and response. The Applicants reserve the right to submit further arguments in support of their above stated position as well as the right to introduce relevant secondary considerations including long-felt but unresolved needs in the industry, failed attempts by others to invent the invention, and the like, should that become necessary.

SUMMARY

For the reasons given above, the Applicants respectfully request reconsideration and allowance of pending claims and that this Application be passed to issue. If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this Application, the Applicants respectfully invite the Examiner to contact the undersigned at the telephone number indicated below or at *wmunck@davismunck.com*.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

DAVIS MUNCK, P.C.

Date: _____

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